

1     ANTI-SPLAY CLOSURE WITH MULTI-STEPPED REMOVAL COUNTERBORE

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3                   Cross-Reference to Related Application

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5           This is a continuation-in-part of co-pending U. S.  
6 Patent Application, Serial No. 10/236,123 filed September 6,  
7 2002 for HELICAL WOUND MECHANICALLY INTERLOCKING MATING  
8 GUIDE AND ADVANCEMENT STRUCTURE, which is now U. S. Patent  
9 No. \_\_, \_\_, \_\_.

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11                   Background of the Invention

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13           The present invention is directed to a closure  
14 mechanism, especially a fastener for use in closing between  
15 spaced arms in medical implants, that includes a multi-  
16 stepped internal bore for improved engagement by an "easy-  
17 out" tool for purposes of removal and an external guide and  
18 advancement structure that interlocks with mating structure  
19 on the implant arms for resisting splaying of the arms due  
20 to forces exerted during installation or later due to injury  
21 or the like.

1        Closure fasteners such as set screws are used in many  
2 ways in order to lock one element of a device relative to  
3 another. Such fasteners are quite important in the art of  
4 medical implants in which it is often necessary to capture  
5 one element of the implant relative to another and to then  
6 secure the two relative to one another to prevent subsequent  
7 movement therebetween. Failure to properly lock two  
8 elements of a medical implant together may result in failure  
9 of the implant and possible serious injury to the patient  
10 within which the implant is placed.

11        With medical implants, it is desirable to have strong  
12 and secure elements which are also very lightweight and low  
13 profile so that the overall implant impacts as little as  
14 possible upon the patient. However, strong and secure are  
15 sometimes contradictory goals compared to lightweight and  
16 low profile. Thus, size, weight and, profile must all be  
17 taken into consideration and minimized, as much as possible,  
18 consistent with effective functioning.

19        In order to provide sufficient strength and friction to  
20 resist movement of the various elements, once the fastener  
21 is seated, it is necessary to apply a fairly substantial  
22 torque to the fastener. While some set screws have  
23 associated driving structure that does not require a driving  
24 head and are torqued without a head, many of the fasteners

1 currently in use in medical implants have a driving or  
2 installation head that breaks away from the remainder of the  
3 fastener at a preselected torque in order to assure that the  
4 fastener is sufficiently torqued to provide the necessary  
5 strength and locking friction. The head is also broken away  
6 in order to assure that the fastener is not over-torqued and  
7 the guide and advancement structure is not stripped.  
8 Further, the head is typically broken away in order to  
9 provide the low profile and light weight that is desired in  
10 such fasteners.

11 Because the driving head is typically broken away and  
12 because it is sometimes necessary to remove the fastener  
13 after implantation and setting thereof, some mechanism must  
14 be provided in order to securely engage and remove the  
15 fastener. Various structures have been provided for this  
16 purpose in prior art devices. The prior art structures have  
17 had varying degrees of success, but have typically been most  
18 effective in fasteners having a diameter that is  
19 comparatively large, such as 8 to 10 millimeters, because  
20 such larger fasteners provide greater surface and volume to  
21 allow the placement of removal structure of one kind or  
22 another on or in the fastener.

23 So-called "easy-outs" are self-tapping, reverse  
24 threaded extraction tools which are commonly employed to

1 remove bolts and screws used in various mechanical devices  
2 where no other means for gripping the fastener is available.  
3 Such devices have especially been used to remove bolts of  
4 which the heads have been broken off or otherwise damaged.  
5 A bore is typically drilled into the broken-headed bolt, and  
6 the easy-out is threaded into the bore in the same direction  
7 as the direction of removal of the bolt. With proper usage  
8 and often times some degree of luck, the easy-out eventually  
9 seizes within the bore, and the easy-out and bolt, as a  
10 unit, are rotated counterclockwise to attempt to remove the  
11 bolt. The term "easy-out" is somewhat of a misnomer in that  
12 they are frequently very difficult tools to utilize. This  
13 is especially true when dealing with closures, fasteners or  
14 set screws of the size used in medical implants which often  
15 range from 5 to 10 millimeters in diameter.

16       It has been found that fasteners of this size with a  
17 conventional axial bore are often not removable by an easy-  
18 out, because the easy-out has too little edge or surface  
19 upon which to grip. Further, the edge that has been  
20 previously provided is often torn away by use of the easy-  
21 out, to a point where there is less and less of an edge or  
22 surface to grip with each subsequent attempt. Consequently,  
23 it is desirable to produce a closure or fastener having a  
24 head that breaks away from a base of the fastener at a

1 preselected torque yet provides a highly gripable surface or  
2 edge in the fastener for use in conjunction with an easy-out  
3 design.

4       Another inherent problem in certain medical implants  
5 with closures of a conventional type is that such fasteners  
6 typically utilize threads which are referred to as V-threads  
7 or threadforms. The outer surfaces of a cross-section of V-  
8 threads form a V-shape. V-threads work reasonably well in  
9 devices where a bore is provided that completely surrounds a  
10 fastener and has a mating thread that mates with the thread  
11 of the fastener. However, many medical implants, such as  
12 open headed bone screws and open headed hooks, do not  
13 provide for a bore that will entirely encircle the closures  
14 that closes the head and locks a rod therein. In such  
15 implants, the closure spans between a pair of discontinuous  
16 threaded surfaces. When V-thread fasteners are utilized for  
17 this purpose, the forces exerted by the fastener closure  
18 during torquing are partially parallel to the axis of  
19 rotation of the closure and partially radial, extending  
20 outwardly from the closure. The radial outward forces can  
21 and frequently do spread or splay the arms of the head  
22 within which the closure is being torqued to an extent which  
23 allows the closure to slip at a torque which is less than  
24 desired.

1       Buttress-type threads have been utilized for the  
2   purpose of reducing the radial outward forces that are  
3   exerted by the threads. In buttress-type threads, the  
4   trailing surface of the thread normally has a cross-section  
5   with an edge that is effectively perpendicular to an axis of  
6   rotation of the closure. Sometimes such surfaces are  
7   referred to as flat, but normally the surface receiving the  
8   driving forces has a slight inclination of 5 to 10 degrees  
9   from perpendicular to the axis of rotation so that a  
10  smaller, but yet still substantial, force is exerted  
11  radially outward by the buttress thread, as compared to the  
12  V-shaped thread.

13       Furthermore, reverse angle threads are sometimes  
14  utilized. While such threads do not transmit an outward  
15  radial force on installation, they still provide only an  
16  interference type connection and have linear surfaces where  
17  forces are transferred, so that if an accident or the like  
18  applies strong splaying forces, the surfaces simply slide  
19  sideways and do not positively interlock or interdigitate.

20       Consequently, it is also desirable to provide a closure  
21  of this type including a guide and advancement structure  
22  designed to be resistant to splaying of the arms and that  
23  works in combination with other elements of the closure to

1 allow rotation and driving for installation and rotation for  
2 removal.

3

#### 4 Summary of the Invention

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6 The present invention provides a fastener or closure  
7 for use particularly with an open-headed bone screw, hook or  
8 other implant. The closure has a cylindrical base and a  
9 driving or installation head that is separable from the base  
10 at a preselected torque at a breakaway region or along a  
11 breakaway line. A bore extends axially through the head and  
12 partially into the base from a trailing end thereof. The  
13 bore is multi-stepped, diminishing in diameter in steps  
14 toward a forward or leading end of the closure to form  
15 multiple bores and shoulders intersecting so as to define at  
16 least a pair of spaced circular edges. The circular edges  
17 provide multiple engagement structures for a self-tapping,  
18 reverse threaded screw removal tool, commonly known as an  
19 easy-out. The threads of the easy-out cut into the  
20 shoulders at the circular edges of the multi-stepped bore to  
21 enhance engagement of the easy-out with the closure to  
22 thereby facilitate removal of the closure from the open-  
23 headed bone screw after the installation head has been  
24 broken from a body of the closure.

1       In the present invention, the closure is provided with  
2   a non-threaded helical wound guide and advancement structure  
3   for securing a closure in a receiver of the bone screw.

4   Preferably, the receiver is a rod receiving channel of an  
5   open-headed bone screw, hook, or other medical implant in  
6   which the channel has an open top and is located between two  
7   spaced apart arms forming the open head of the bone screw.

8       The closure body is cylindrical and has an external  
9   guide and advancement flange extending helically about the  
10  base relative to a central closure axis. The flange  
11  preferably has a compound, anti-splay type of contour which  
12  cooperates with complementary mating internal guide and  
13  advancement structures formed into the inner surfaces of the  
14  spaced apart arms forming the open head of the bone implant  
15  screw. The flange has such a compound contour as to form an  
16  inward anti-splay surface component on the closure body  
17  which faces generally inward toward the closure axis. The  
18  mating guide and advancement structures of the bone screw  
19  head have a complementary contour to the closure flange  
20  including an outward anti-splay surface component which  
21  faces, generally away from the closure axis as the closure  
22  is being installed therein.

23       Preferably, the inward anti-splay surface component may  
24  be formed by an enlarged region near an outer periphery of



1 the closure flange at a crest of the flange. The outward  
2 anti-splay surface components are formed by an enlarged  
3 region near an outer periphery of the mating guide and  
4 advancement structure of the bone screw head. The  
5 complementary anti-splay surface components of the closure  
6 and head engage during insertion of the closure into the  
7 receiver between the arms by rotation thereof and then  
8 interlock and cooperate to resist splaying tendencies of the  
9 arms of the head when the closure is strongly torqued into  
10 the open head of the bone screw or when outside forces are  
11 applied due to accident, over exertion or the like.

12 In use, the closure and open-headed bone screw are used  
13 to anchor a spinal fixation member, such as a rod, by  
14 implanting the bone screw into a bone and clamping the rod  
15 within the head of the bone screw using the closure. In  
16 order to enhance clamping engagement of the rod, the closure  
17 body is also preferably provided with structural features  
18 which cut into the surface of the rod to thereby reduce the  
19 likelihood of translational or rotational movement of the  
20 rod relative to the bone screw. The closure is preferably  
21 provided with a centrally located set point and a  
22 peripherally located "cup point", set ring, or V-ring on the  
23 leading end of the closure body to cut into the surface of  
24 the rod when the closure is tightly torqued into the head of

1 the bone screw. In some embodiments, the body is also  
2 provided with a central axial point on the leading end  
3 thereof.

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6 Objects and Advantages of the Invention

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8 Therefore, objects of the present invention include  
9 providing an improved closure for use with an open headed  
10 bone screw; providing such a closure having a cylindrical  
11 base and a driving or installation head that breaks away  
12 from the base at a breakaway region to provide a low or  
13 minimized profile subsequent to installation of the closure;  
14 providing such a closure having an axially extending bore  
15 that passes partially through a body of the closure from a  
16 trailing surface thereof and that has a stepdown region in  
17 the body wherein the bore passes from a region of a larger  
18 diameter to a region of a smaller diameter so as to form  
19 multiple spaced edges; providing such a closure in which the  
20 bore is multi-stepped with component bores diminishing in  
21 diameter in steps toward a forward end of the closure to  
22 provide cylindrical bores intersecting planar shoulders at  
23 respective circular edges; providing such a closure with  
24 such a multi-stepped bore to enhance secure engagement of

1 the closure by a self-tapping, reverse threaded screw  
2 removal tool, such as an easy-out; providing such a closure  
3 in combination with an open headed bone screw implant for  
4 use in anchoring a bone fixation structural member, such as  
5 a rod; providing such a closure and implant combination in  
6 which the open headed bone screw includes a pair of spaced  
7 apart arms forming a rod receiving channel; providing such a  
8 closure and implant combination including a helical wound  
9 guide and advancement flange on a body of the closure and  
10 mating internal guide and advancement structures tapped into  
11 inner surfaces of the bone screw head which, when rotatably  
12 joined, interlock and cooperate to resist tendencies of the  
13 arms to splay when the closure is torqued tightly into  
14 clamping engagement with a rod positioned in the channel or  
15 when other forces are applied to the implant; providing such  
16 a combination including features to enhance setting  
17 engagement of the closure with a rod in the bone screw  
18 channel; providing such a combination in which a forward end  
19 of the closure is provided with a central set point and a  
20 peripheral V-ring to cut into the surface of the rod when  
21 the closure is securely torqued, to prevent translational  
22 and rotational movement of the rod relative to the bone  
23 screw; and providing such an anti-splay closure with a  
24 multi-stepped counterbore which is economical to

1 manufacture, which is secure and efficient in use, and which  
2 is particularly well adapted for its intended purpose.

3 Other objects and advantages of this invention will  
4 become apparent from the following description taken in  
5 conjunction with the accompanying drawings wherein are set  
6 forth, by way of illustration and example, certain  
7 embodiments of this invention.

8 The drawings constitute a part of this specification,  
9 include exemplary embodiments of the present invention, and  
10 illustrate various objects and features thereof.

11

12 Brief Description of the Drawings

13

14 Fig. 1 is an enlarged perspective view of an anti-splay  
15 closure having an installation break off head with a multi-  
16 stepped removal counterbore in accordance with the present  
17 invention.

18 Fig. 2 is a side elevational view of the closure at a  
19 further enlarged scale.

20 Fig. 3 is a top plan view of the closure and  
21 illustrates details of the multi-stepped removal counterbore  
22 with the installation break off head in place.

1        Fig. 4 is a bottom plan view of the closure  
2 illustrating a set point and V-ring on a forward end of a  
3 body of the closure.

4        Fig. 5 is a cross sectional view of the closure taken  
5 on line 5-5 of Fig. 3 and illustrates internal details of  
6 the multi-stepped removal counterbore and helically wound  
7 guide and advancement structures.

8        Fig. 6 is a fragmentary side elevational view at a  
9 reduced scale of the closure in combination with an open  
10 headed bone screw.

11       Fig. 7 is a view similar to Fig. 6 and illustrates  
12 separation of a breakaway installation head of the closure.

13       Fig. 8 is a greatly enlarged cross sectional view of  
14 the closure of the present invention positioned in clamping  
15 relationship within an open headed bone screw and  
16 illustrates details of an anti-splay guide and advancement  
17 structure of and bone screw head and also illustrating an  
18 east-out tool engaging the multi-stepped removal counterbore  
19 for removing the closure body from the bone screw.

20       Fig. 9 is a greatly enlarged top plan view of the  
21 closure within the open headed bone screw.

22

23                    Detailed Description of the Invention

24

1       As required, detailed embodiments of the present  
2 invention are disclosed herein; however, it is to be  
3 understood that the disclosed embodiments are merely  
4 exemplary of the invention, which may be embodied in various  
5 forms. Therefore, specific structural and functional  
6 details disclosed herein are not to be interpreted as  
7 limiting, but merely as a basis for the claims and as a  
8 representative basis for teaching one skilled in the art to  
9 variously employ the present invention in virtually any  
10 appropriately detailed structure.

11       Referring to the drawings in more detail, the reference  
12 numeral 1 generally designates an anti-splay fastener or  
13 closure with a multi-stepped counterbore 2. The closure 1  
14 generally includes a plug or body 4 and a breakaway  
15 installation head 6. The body 4 is used in cooperation with  
16 an open headed bone implant screw 8 (Figs. 6 and 7) to form  
17 an implant anchor assembly 9 to secure or anchor a spinal  
18 fixation member or rod 10 with respect to a bone 12, such as  
19 a vertebra.

20       The bone screw 8 includes a threaded shank 14 for  
21 threadably implanting into the bone 12 and an open head 16  
22 formed by a pair of spaced apart arms 18 defining a U-shaped  
23 channel 20 therebetween to receive the rod 10. Inner  
24 surfaces of the arms 18 have internal guide and advancement

1 structures 23 (Fig. 8) tapped, or otherwise formed, therein.  
2 The head 16 has grip indentations 21 (Fig. 8) to facilitate  
3 gripping the bone screw 8 by an appropriate tool (not shown)  
4 during manipulation for implantation of the bone screw 8  
5 into the bone 12.

6 The body 4 is cylindrical in external shape about a  
7 closure axis 25 (Fig. 2) and has a forward, leading, or  
8 inner end 27 and a rear, trailing, or outer end 28. The  
9 breakaway head 6 is connected to the body 4 at the rear end  
10 28 by way of a weakened breakaway region or ring 30 formed  
11 by selectively reducing the wall thickness of the closure 1  
12 to weaken the region. The breakaway ring 30 is thinned in  
13 such a manner that it fails at a selected relative torque  
14 between the head 6 and the body 4, as a result of torque  
15 applied to the head 6 to drive and tighten the body 4 within  
16 the bone screw 8. As illustrated, the breakaway head 6 has  
17 a hexagonal outer surface 31 to facilitate non-slip  
18 engagement by an installation tool (not shown) of a  
19 conventional socket type. The head 6 is also provided with  
20 a set of tool slots 32 for alternative or more positive non-  
21 slip engagement of the head by the installation tool.  
22 Separation of the head 6 from the body 4, as shown in Fig.  
23 7) is desirable to control or limit torque applied by the  
24 body 4 to the rod 10 within the bone screw head 16 and to

1 provide a low profile joint between the body 4 relative to  
2 the bone screw 8, especially where the top of the body 4,  
3 after breakoff of the head 6, is at or below the top of the  
4 arms 18.

5 Referring to Fig. 8, the body 4 is provided with an  
6 anti-splay guide and advancement structure or flange 35 for  
7 cooperation with the mating guide and advancement structures  
8 23 in the open head 16 of the bone screw 8, to thereby  
9 interlock the body 4 with the head 16 to clamp the rod 10,  
10 after the body 4 is rotated into and received between the  
11 arms 18 by rotational engagement of the guide and  
12 advancement structures 35 and 23. The closure 4, after  
13 insertion in the bone screw head 16 resists splaying of the  
14 arms 18 of the head 16. The guide and advancement flange 35  
15 extends helically about the body 4 from near the rear end 28  
16 to near the forward end 29 thereof. The illustrated guide  
17 and advancement flange 35 has an enlarged outer bead 37 near  
18 a periphery thereof and located on a trailing surface 38  
19 thereof, which extends along an outer periphery or crest of  
20 the guide and advancement flange 35 to form a compound  
21 contour including an inward anti-splay surface 39 which  
22 faces, or has a component or projection which faces,  
23 generally toward the body axis 25. The trailing surface 38  
24 of the flange 35 is referenced to a forward direction of



1 advancement of the body 4 into the bone screw 8 and is  
2 directed away from the forward end 27 of the body 4.

3 In a similar manner, the illustrated mating guide and  
4 advancement structures 23 on the bone screw arms 18 are  
5 enlarged near the radially outward peripheries thereof to  
6 form compound contours, on engaging surfaces 41 of the  
7 mating structures 23, including outward anti-splay surfaces  
8 43 which face, or have components or projections which face,  
9 generally away from the body axis 25.

10 The inward anti-splay surfaces 39 of the body 4 engage  
11 the outward anti-splay surfaces 43 of the head 16 when the  
12 body 4 is advanced into the head 16 to resist any tendencies  
13 of the arms 18 of the head 16 to splay or be urged outward,  
14 away from the body 4, in reaction to relative torque between  
15 the body 4 and the screw head 16 or other radially acting  
16 forces that operably try to splay or separate the upper ends  
17 of the arms 18. Although the compound contours forming the  
18 anti-splay surfaces 39 and 43 are shown to be on the  
19 surfaces shown, it is conceivable that the compound contours  
20 could be formed on the leading surfaces of the body flange  
21 structure 35 and appropriate mating structure. Furthermore,  
22 the contour along the surfaces of the guide and advancement  
23 structure can be varied substantially under the invention to  
24 provide a region spaced from the closure wall and arm walls

1 that projects axially in one direction or the other with  
2 mating structure on the opposite so that the body 4 and arms  
3 18 are interlocked together once the body 4 is rotated into  
4 position between the arms 18. Other configurations of the  
5 interlocking flange and mating structures in accordance with  
6 the present invention are found in U.S. application for  
7 patent Serial No. 10/236,123 which is now U.S. Patent  
8 \_\_, \_\_, \_\_ and which is incorporated herein by reference.

9 Referring to Figs. 5, 8, and 9, the closure 1 is  
10 provided with the multi-stepped bore or counterbore 2 to  
11 form multiple circular edges 47 for enhanced engagement by  
12 threads 49 of a reverse threaded, self-tapping closure  
13 removal tool 51, known as an easy-out.

14 The illustrated multi-stepped bore 2 is formed by a  
15 plurality of cylindrical component coaxial bores 53 having  
16 cylindrical surfaces which diminish in diameter in steps in  
17 a direction toward the forward end 27 of the body 4. The  
18 bores 53 create shoulders 55 which intersect successive  
19 bores 53 at the circular edges 47. The edges 47 provide  
20 locations for the self-tapping threads 49 of the easy-out 51  
21 to cut into the shoulders 55 to more securely engage the  
22 easy-out 51 with the body 4, than if a single bore of an  
23 appropriate size and angle were employed. The easy-out 51  
24 is threaded in a helical direction opposite that of the

1 guide and advancement flange 35 and mating structures 23 so  
2 that threading the easy-out into the bore 2 and continued  
3 rotation in the direction of engagement by the easy-out 51  
4 further engages the easy-out and initiates counterclockwise  
5 rotation and extraction of the body 4 from the open head 16  
6 of the bone screw 8. The multi-stepped bore 2 increases the  
7 likelihood that the easy-out 51 will grasp the body 4 during  
8 the entire process without slippage. Once the body 4 has  
9 been loosened from the head 16, it may be rotated out of the  
10 head 16.

11 The body 4 also includes formations to enhance clamping  
12 and securing engagement of the body 4 with the rod 10.  
13 Referring to Figs. 5 and 8, the illustrated body 4 includes  
14 a centrally located set point 58 and a peripherally  
15 extending V-ring or set ring 60 on the forward end 27. The  
16 set point 58 and V-ring 60, also known as a "cup point", are  
17 provided to operably cut into the outer surface of the rod  
18 10 when the body 4 is strongly torqued into the bone screw  
19 head 16. The point 58 and V-ring 60, when set, reduce the  
20 likelihood of rotational and translational movement between  
21 the rod 10 and the bone screw 8.

22 It is to be understood that while certain forms of the  
23 present invention have been illustrated and described

1 herein, it is not to be limited to the specific forms or  
2 arrangement of parts described and shown.

3